

## **REMARKS**

### **Introduction**

Claims 11-12 and 25-26 are pending. Claim 11 has been amended. Support for the amendments can be found throughout the specification, for example, in the original claims (e.g., claim 19) and in paragraphs [0154]-[0169].

Claims 1-10, 13-24, and 27-28 have been cancelled without prejudice to the subject matter therein. Applicant expressly reserves the right to pursue the subject matter of the cancelled claims in this application or in another application.

### **Amendments to the Specification/Sequence Listing Statement**

The Examiner has noted that the specification fails to comply with the requirements of 37 C.F.R. §1.821 through 1.825 because it lacks SEQ ID NOs. The amendments included herein do not add new matter and are believed to correctly identify the sequences listed in the specification. Withdrawal of this objection is respectfully requested.

Further, Applicant has previously stated that the paper copy and electronic copies submitted and requested to be entered on April 9, 2007 are the same and again reiterates that these copies are the same and should be entered into the application (if it has not already been done).

### **Rejections under 35 U.S.C. §112**

The Examiner has rejected claims 11-12 and 25-26 under 35 U.S.C. §112 as allegedly failing to comply with the enablement requirement. Applicant traverses.

To expedite prosecution, claim 11 has been amended to require that the compounds decrease the neurodegenerative diseases and/or disorders. This amendment was suggested by the Examiner on page 3 of the Office Action and is believed to overcome this rejection.

The Examiner has also rejected the claims as allegedly lacking sufficient enablement for using various animal models in the claimed methods to screen for modulators of neurodegenerative diseases and/or disorders. Applicant traverses.

To expedite prosecution, claim 11 has been amended to limit the animal model used in the claimed screening method to flies, e.g., *Drosophila melanogaster*. The specification demonstrates a relationship between dysregulated HIF3a gene expression and the pathology of neurodegeneration. See, e.g., Fig. 38 and pgs. 41 and 59-60 of WO 2005/059562 (the '562 publication<sup>1</sup>). The specification further discloses how to make the genetically altered fly claimed on page 26 of the '562 publication. The sequences and the structure of the construct are given on page 57, example xii ("A 1942 bp EcoRI/XhoI fragment of the HIF3a sv3 cDNA (SEQ ID NO. 8) containing the entire open reading frame of HIF3a sv3 (SEQ ID NO.30, SEQ ID NO.4) and fused in frame to a myc-tag (aa EQKLISEEDL) at the 3' end was subcloned into the EcoRI/XhoI restriction sites of the vector pUAST downstream of the GAL4-binding sites UAS (Brand and Perrimon, Development 1993, 118: 401-15)"). Furthermore, the specification also cited the Greeve *et al.* paper (2004, copy attached) which would allow one of skill in the art to generate the BACE fly model.

Applicant has also described the phenotype correlating with symptoms of neurodegeneration in Figure 42 and on pages 43 and 59-60 of the '562 publication. The specification shows that the flies described model neurodegenerative disease in humans. For example, the appearance of Abeta plaques is one indicator of neurodegeneration as well as the degeneration of photoreceptor cells. See, e.g., pgs. 43-44, 59-60, and Figs. 42-44 of the '562 publication.

Taken together, the information from the specification and in Greeve *et al.* would enable one of skill in the art to generate the HIF3a/BACE flies claimed and use them in the claimed methods. Therefore, the rejections under 35 U.S.C. §112 are improper in view of the amended claims and their withdrawal is respectfully requested.

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<sup>1</sup> The pending application is a national stage entry of PCT/EP2004/053573 which published as WO 2005/059562.

Rejection under 102

The Examiner has rejected claim 11 as allegedly being anticipated by Heidbreder and/or Makino. *See* Office Action at pgs. 8-9 for citations. Applicant traverses.

To expedite prosecution, claim 11 has been amended to claim the administration of compounds to a genetically altered *Drosophila melanogaster* fly. As the Examiner notes, both Heidbreder and Makino are directed to testing in mice and not flies as the amended claims require. *See* Office Action at page 9, first and third paragraphs. For at least this reason, amended claim 11 is not anticipated by either Heidbreder or Makino. Withdrawal of the rejection under 35 U.S.C. §102(a) is respectfully requested.

**CONCLUSION**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR § 1.17, including extension of time fees pursuant to 37 CFR § 1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

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Respectfully submitted,

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